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EXAMINER

REDDING, DAVID A

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/633,448

Applicant(s)

JURY ET AL.

Examiner

David A. Redding

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-103 is/are pending in the application.
- 4a) Of the above claim(s) 1-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 94-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/18/05; 4/25/05; 11/25/05
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Applicant's election with traverse of claims 94-103 in the reply filed on 11/25/05 is acknowledged. The traversal is on the ground(s) that the search for all of the identified species would not be burdensome. This is not found persuasive because based on the different classification of the species and required search for each species the search would be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 97 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 72 of copending Application No.

10/457,049.

Although the conflicting claims are not identical, they are not patentably distinct from each other because adding a gas to the reaction chamber would inherently alter the pH as claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 100 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-27,32-37,40,45,46,73-75 of copending Application No. 10/644,046. Although the conflicting claims are not identical, they are not patentably distinct from each other because a control means is obviously inherent to the device of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 97,98, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2,5,80,81,86 of copending Application No. 10/664,068. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are broader and therefore anticipated by the claims of the '068 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 94,99,100 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,071,478 (Chow).

Chow discloses a microfluidic device (Fig. 1, col.1, lines 43-59) which comprises a substrate equipped with a microfluidic channel having a thermal treatment chamber (52) and a reaction chamber (50). The channels are equipped with inlets (60) and outlets (60) which are considered to be connectable to a source of starting material. The device is also equipped with a heating/cooling means (36).

The reference discloses that the device may be equipped with heat detectors, flow detectors and sensors for measuring pH, electrical potential or current (col.3, lines 57-67). The device is also equipped with control circuitry and software for controlling functions of the assay, including temperature (col.5, lines 24-35).

Claims 94,99,100, are rejected under 35 U.S.C. 102(e) as being anticipated by USP 5,928,880 (Wilding et al.).

Wilding et al. disclose a mesoscale device (figure 1) comprising a unit (10) which may be interfaced with an appliance (30). The unit (10) includes inlet (14), channel or chamber (22) and outlet (16). The appliance (30) includes a sample transfer opening (35) whereby reagents or samples can be transferred from a sample or reagent delivery source.

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Also the appliance (30) includes an outlet (36) whereby solutions can be transferred to another holding chamber (see figure 4). The dimensions of the unit (10) and appliance are within the range claimed (col.7, lines 26-67). The reference further discloses embodiments in which the unit or appliance includes pressure sensors (59a, 59b), heating/cooling elements (95) connected to a control element (90) for controlling the temperature (col.12, lines 51-67; col.15, lines 50-63). In one embodiment the product of a reaction is recovered via outlet (94), and in another embodiment reagent solution is recovered via an outlet (170) and transferred to another storage device (col.18, lines 41-55).

Claims 97,98,101-103, are rejected under 35 U.S.C. 102(e) as being anticipated by WO99/55827.

The WO document discloses a microfluidic cell culture device (18) which consists of a disk comprised of an upper and lower polymeric surface. In the simplest form, the device is produced as two complementary parts, one or each carrying molded structures which, when affixed together, form a series of interconnected micro-channel elements (6) within the body of the solid disc. Each of the micro-channels (6) are connected at one end to a common sample reservoir (9) and at the opposing end to a common waste (10). Looking at figures 2 and 3 one sees that each of the micro-channels includes a cell growth chamber (2) and an assay chamber (3). The range of sizes of the chambers includes a volume of less than 1 ml. (example # 1 and #4).

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To provide cultured cells with means for obtaining oxygen for metabolism and to use CO₂-buffered media, one or more components of the device may be constructed from a gas permeable film or membrane to allow gas exchange from the chamber to exterior of the chamber (col.3, lines 65 thru col.4, line 14). As such the exterior of the membrane covered chamber is considered to constitute a source of gas which is able to alter the pH of the chamber. The membranes are considered to be size-selective.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

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Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 94 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/55827 in view of USP 6,071,478 and USP 5,252,294 (Kroy).

The WO reference discloses a microfluidic device for cell culturing in a chamber having a volume less than 1ml. The reference discloses that the device be capable of detection and measurement of cellular activity, cellular parameters and biochemical processes such as cellular metabolism. One skilled in the art recognizes that cellular activity, parameters and metabolism is monitored by measuring pH, temperature, pressure and oxygen concentration. The Chow patent discloses a microfluidic device which incorporated pH, temperature, and pressure sensors for monitoring an assay (col.3, lines 57-67). The Kroy patent discloses the use of an electrochemical sensor for monitoring oxygen content (figure 13) within a microfluidic device. Accordingly, it would have been obvious to one skilled in the art to provide all of a temperature, pH, oxygen concentration and pressure sensors as disclosed in the Chow and Kroy patents into the microfluidic device of the WO reference in view of the known use in the Choy and Kroy patents.

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Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,928,880 (Wilding et al.).

In one embodiment in the Wilding et al. patent the product of a reaction is recovered via outlet (94), and in another embodiment reagent solution is recovered via an outlet (170) and transferred to another storage device (col.18, lines 41-55). The reference is silent as to the size of the storage device which is connected to the outlet. However, in the absence of unexpected results the size of the storage device is considered to be obvious.


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The USP 6,689,594 is related to the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Redding whose telephone number is 571-272-1276. The examiner can normally be reached on Mon.-Fri. 6:00 - 3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David A Redding
Primary Examiner
Art Unit 1744

DAR